REMARKS

In response to the restriction requirement, applicant chose the group of claims drawn to a method for delivering a defibrillation shock, an election which is hereby affirmed. The claims 30-45 drawn to a method for applying electrotherapy in an automatic external defibrillator and to a defibrillator have been withdrawn. Additional claims drawn to a method for delivering a defibrillation shock and based upon the claims of the priority provisional applications have been added to fully claim the present invention.

The Examiner has objected to a number of informalities in the specification in paragraphs spanning pages 8-9 which describe Figs. 3 and 4. These informalities have been corrected as the Examiner has suggested and several other wording changes made to more clearly describe what is shown in the drawings. In addition, the paragraph beginning on page 10, line 7 has been amended with language from the corresponding paragraph beginning on page 7, line 19 of the 60/476,981 priority application. It is respectfully submitted that these informalities have now been corrected.

The Examiner has made a number of objections to the drawings which have been addressed in this Amendment. In the enclosed Replacement Sheet for Fig. 1, the victim is now designated by reference numeral "2". The voice circuit and speaker 41 in Fig. 2 is now described in the paragraph beginning on page 6, line 20, by incorporating the subject matter of the description of this element found in the 60/476,981 priority application on page 7, lines 1-3. The incorrect reference numeral "10" in Fig. 3 has been corrected to "50".

The description of Fig. 4 in the specification is of the Fig. 4 filed with the 60/433,375 priority application, whereas the Fig. 4 shown in the application is the Fig. 4 of the 60/476,981 priority application. Accordingly, the enclosed Replacement Sheet for Fig. 4 is the Fig. 4 of the 60/433,375 priority application. Since the text description now matches the correct drawing, it is respectfully submitted that the objection to Fig. 4 can be withdrawn.

Figs. 5 and 6 are drawings from the 60/476,981 priority application, which are not described in the present specification, which, as previously mentioned, is that of the 60/433,375 priority application. Accordingly, these drawings are hereby canceled from the

application to overcome the objection to them. It is respectfully submitted that, with these changes, the drawings and specification are correct and consistent with each other.

Claims 25-28 were rejected under 35 U.S.C. §102(e) as being anticipated by US patent application publication no. 2004/0162585, now US Pat. 6,961,612 (Elghazzawi et al.) Amended Claim 25 describes a method for delivering a defibrillation shock using a defibrillator, the method comprising the steps of (a) having the defibrillator initiate a cardio-pulmonary resuscitation (CPR) interval; (b) prior to an end of the cardio-pulmonary resuscitation (CPR) interval, analyzing the ECG signal for signal corruption and, if a cessation or absence of CPR precordial compressions is indicated by substantially no signal corruption; (c) analyzing an ECG signal prior to the end of the originally initiated cardio-pulmonary resuscitation (CPR) interval to determine if a defibrillation shock is needed; and, (d) delivering a defibrillation shock if the analyzing step indicates that a defibrillation shock is needed. One of the desires in protocols for resuscitation of cardiac arrest victims is to be able to analyze the patient's ECG for indication that a resuscitating shock is needed whenever such analysis is possible. This analysis takes valuable time during a rescue, as an interval of several seconds of uninterrupted ECG acquisition is generally needed to make an accurate assessment of whether a defibrillating shock is needed. But many rescue protocols also call for CPR to be delivered when appropriate during a rescue. The force of the chest compressions of CPR renders the ECG signal unuseable for an accurate determination of whether a shock is needed, however. Thus, as indicated in paragraph [0003] of Elghazzawi et al., the protocol of many AEDs is to wait until the CPR period times out before resuming acquisition of ECG signals. The rescuer is prompted at the end of the CPR interval to avoid touching or moving the victim so that a reliable ECG signal can be acquired for reliable shock analysis.

CPR can go on for several minutes and it would be desirable to be able to determine during the CPR interval if a defibrillating shock was needed. If so, the CPR interval could be prematurely ended and the shock delivered. This would be particularly desirable in a situation where the patient has been defibrillated but, during subsequent CPR, the patient lapses back into fibrillation. Hence some AEDs are more aggressive in their signal acquisition and try to acquire sequences of ECG signals for analysis during the CPR interval.

Elghazzawi et al. describe one such aggressive approach in which ECG analysis runs continuously during the CPR interval. As each embodiment of Elghazzawi et al. states, the ECG analysis task runs simultaneously and continuously during a CPR preprogrammed interval in the hope that a useful ECG signal can be acquired between chest compressions. This is known in the industry as a "look between" approach. What Elghazzawi et al. do is reset their ECG analysis algorithm each time a chest compression is detected. If enough time passes between compressions a useful ECG sequence may be acquired and used to make a shock decision. However, if another chest compression occurs before enough time has passes to acquire sufficient useful ECG data, the algorithm is reset by the new chest compression and the process continues. It is the hope of Elghazzawi et al. that useful ECG data for analysis can be acquired during the CPR interval and a shockable rhythm identified if present. As stated in paragraph [0025], if the between-the-compressions analysis determines that a shock is needed to defibrillate recurring fibrillation, for example, the AED alerts the rescuer that a shock is needed, the CPR interval is terminated and the AED switches to the foreground shock delivery state.

The flaw in this approach is that the American Heart Association guidelines for CPR call for chest compressions to be delivered at a rate of 100 compressions per minute. An AED with a CPR interval will thus prompt the rescuer to deliver compressions at this rate, usually accompanied by a metronome tone at this rate and prompts to urge the rescuer to "press faster" or "press slower" to maintain the rate. It is apparent that, when chest compressions are being administered at 100 compressions per minute, the ability to acquire several seconds of continuous ECG signals uncontaminated by compression artifacts is nil. The hope of Elghazzawi et al. to acquire such an ECG data is thus illusory, absent some ability to overcome the artifact contamination. The present inventor has recognized this reality and developed an inventive defibrillation method which only acquires ECG signals after the CPR interval has ended. But he has further recognized that there may be instances where the rescuer may not administer compressions continuously for the entire predetermined 1-3 minute CPR interval. The rescuer may tire from the exertion of the CPR activity and take a break, or interrupt CPR delivery due to a distraction or some other reason. In those instances where the rescuer stops CPR delivery prematurely, his inventive technique

monitors for such cessation of the CPR compressions. When premature CPR cessation is detected, his technique will end the CPR interval before its predetermined expiry and analyze the now-uncontaminated patient ECG signals. When the analysis determines that a shock is advised the defibrillator will arm itself for shock delivery and deliver the shock, in advance of the predetermined CPR interval expiration. Thus, the inventive technique takes advantage of a premature end to the CPR interval to analyze for VF and deliver a shock as quickly as the situation permits. There is no waiting to the end of the predetermined time period of the CPR interval as is done in the conventional approach. And there is no analysis of ECG signals while CPR is underway, as proper CPR administration will render those signals unuseable. The present invention does not have "CPR detection and ECG analysis running simultaneously and continuously during a CPR preprogrammed interval," as is done by Elghazzawi et al.

The inventive technique is spelled out in Claim 25 which starts by having the defibrillator initiate a CPR interval during which chest compressions are administered. Prior to the scheduled end of the CPR interval, the ECG signal is analyzed for signal corruption caused by chest compressions. An absence of signal corruption during the CPR interval indicates that chest compressions have ceased prematurely. Unlike Elghazzawi et al., which uses a separate sensor to detect when a rescuer is delivering CPR chest compressions to the patient, the present invention needs no additional sensor. Instead, the inventive technique uses the ECG signal itself, looking at the noise of the ECG processor for signs of signal corruption. The sudden appearance of a high level of noise in the ECG signal indicates that chest compressions are underway, for instance. If no signal corruption is found for a period of time, the defibrillator moves to its shock therapy mode and begins to analyze the ECG signal for ventricular fibrillation and the need for a defibrillation shock. When the VF analysis indicates that a shock is needed, the defibrillator proceeds to deliver a shock to defibrillate the patient. Thus, there is no attempt to shorten a CPR interval so long as CPR is continuing, but if the CPR is ended prematurely, the defibrillator recognizes this condition and moves to the ECG analysis and shock delivery mode of operation. It is respectfully submitted that amended Claim 25 is not anticipated by Elghazzawi et al. Claims 26-29 should now be allowable by reason of their dependency from Claim 25.

New Claim 46 describes a method for delivering a defibrillation shock using a defibrillator, the method comprising the steps of prompting a start of a CPR therapy interval; detecting an indication of CPR precordial compression cessation during the CPR therapy interval; and arming the AED for defibrillation shock delivery based on the detected cessation of precordial compressions detected during the CPR therapy interval. As above, this method does not interrupt a CPR therapy interval or continually try to analyze ECG signals between chest compressions as Elghazzawi et al. do. Instead, the method prompts the rescuer to start a CPR therapy interval and monitors for a cessation of precordial compressions during the initiated CPR therapy interval. If it is detected that precordial compressions have ceased before the scheduled end of the CPR interval, the AED is armed for shock delivery based on the detected cessation of precordial compressions during the originally scheduled CPR therapy interval. In addition to the foregoing reasons for patentability over Elghazzawi et al., the Elghazzawi et al. patent application does not teach the arming of an AED for shock delivery based on the detected cessation of compression during a CPR therapy interval. The Examiner points to the mention of charging and shock delivery in paragraph [0003] of Elghazzawi et al., but this is in the background section of the patent application. Nowhere do Elghazzawi et al. indicate when an AED is armed for shock delivery in their approach described in their application. For these reasons it is respectfully submitted that new Claim 46 and its dependent Claims 47-53 are patentable over Elghazzawi et al.

New Claim 54 describes a method for delivering a defibrillation shock using a defibrillator, the method comprising the steps of coupling a plurality of sensors to the patient's body to detect physiological signals of the patient; initiating a predetermined CPR therapy interval during which precordial compressions are to be administered to the patient; monitoring a physiological signal received from at least one of the sensors to detect a cessation of precordial compression administration prior to the end of the predetermined CPR therapy interval; upon detecting a cessation of precordial compression administration prior to the end of the predetermined therapy interval, obtaining ECG signals from a plurality of the sensors; analyzing the obtained ECG signals to determine whether a defibrillation shock is needed; and if the analyzing step determines that a defibrillation shock is needed, delivering

a defibrillation shock to the patient through a plurality of the sensors. The method of Claim 54 monitors for a premature ending of precordial compression administration prior to the end of a previously initiated, predetermined CPR therapy interval. If the monitoring detects that precordial compression administration has ended prior to the end of the predetermined therapy interval, ECG signals are then obtained from a plurality of sensors. There is no wasted effort trying to acquire snippets of ECG information during CPR, as that data is likely to be contaminated by compression artifacts and of insufficient duration for an adequate VF analysis. This is contrary to the teaching of Elghazzawi et al., who are constantly trying to acquire ECG signal data during the administration of CPR. The present invention does not spend effort on such acquisition, but wait until precordial compression has ended. It is then that ECG signals are obtained and analyzed to determine whether a defibrillation shock is need and, if such need is determined, a defibrillating shock is delivered through a plurality of the sensors. As stated in the dependent Claim 57, this method permits initiation of charging for shock delivery in advance of the originally predetermined end of the CPR therapy interval. Accordingly it is respectfully submitted that Claim 54 and its dependent Claims 55-57 are patentable over Elghazzawi et al.

In view of the foregoing amendments and remarks it is respectfully submitted that the informalities in the specification have been corrected, the amended drawings are now consistent with the specification, that amended Claims 25-29 are not anticipated by Elghazzawi et al., and that new Claims 46-57 are patentable over Elghazzawi et al. Accordingly it is respectfully requested that the objections to the specification be withdrawn, the amended drawings be accepted, the rejection of Claims 25-29 under 35 U.S.C. §102(e) be withdrawn and new Claims 46-57 be allowed.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

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